

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Amendments to the Claims and Specification**

Claims 24 and 26 are requested to be cancelled.

Claims 1-5 and 7-23 are currently being amended. Support for these amendments can be found throughout the specification as-filed, such as on page 2, ll. 20-22; and page 26, ll. 32-34.

Claims 27-48 are being added. Support for these new claims can be found though the specification as filed such as on pages 13, 96-98, and 103-104 of the specification.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

The specification has been amended to insert sequence identifiers into Table 1 on page 13 of the specification. No new matter is being added.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. After amending the claims as set forth above, claims 1-23, 25, and 27-48 are now pending in this application. Claims 6 and 25 have been withdrawn. Thus, claims 1-5, 7-23, and 27-48 are pending and should be examined on the merits.

**II. Election/Restriction**

The Examiner has made the restriction requirement final and withdrawn claims 6 and 25 from consideration. Thus, claims 1-5, 7-24, and 26 are pending and being examined on their merits. Applicants respectfully traverse the restriction requirement for at least the reasons already of record.

### **III. Claim Objections**

The Examiner objects to claims 9, 14, 20, 21, and 22, because the acronyms “NOI” and “POI” are not accompanied by the full designation represented by the acronym. Applicants have amended the claims to replace “NOI” and “POI” with “nucleotide sequence of interest” and “protein of interest,” respectively.

The Examiner also objects to claims 10-12, because the claims do not identify the referenced sequences by a sequence identifier number. Applicants have amended Table 1 to contain sequence identifiers and have amended the claims to reference the sequence identifiers included in Table 1, as amended.

Accordingly, Applicants respectfully request the claim objections be withdrawn.

### **IV. Claim Rejections – 35 U.S.C. § 112, first paragraph**

#### **A. Written Description**

Claims 1-2, 5, 7-22, and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the specification does not describe a sufficient number of the claimed variants, homologues, fragments, or derivatives. Applicants respectfully traverse this ground of rejection.

While not acquiescing in the rejection, Applicants have amended the claims to delete the recitation of the phrase “variant, homologue, fragment or derivative thereof”. As amended, the claims recite a “nucleotide sequence with at least 75% homology to SEQ ID No. 1.” Thus, the sequences are structurally defined by an easily quantifiable value. As noted by the examiner, the specification provides a number of specific examples of nucleotide sequences with at least 75% homology to SEQ ID No. 1. In addition, the specification describes ways of obtaining the claimed genus of species, including tests for function. *See, e.g.*, page 24, ll. 22-26; page 25, l. 28 – page 26, l. 20; page 54, l. 29 – page 56, l. 9.

The claims also describe the claimed genus in terms of function. Specifically, the claims do not cover any sequence meeting the structural requirements but instead cover

promoters meeting the structural requirements. When a claimed genus of polynucleotides is defined in terms of both structure and function, a specific recitation of each species is not required. *See In re Wallach*, 378 F.3d 1330, 1333-34 (Fed. Cir. 2004). The art has developed to such a point that such an extensive description is not necessary to demonstrate possession. *Id.*

In light of the functional and structural description of the claimed genus, including working examples, the claimed invention is defined in such a way as to show possession of the invention at the time of filing. Accordingly, Applicants respectfully request reconsideration and withdrawal of this ground of rejection against claims 1-2, 5, 7-22, and 26 under 35 U.S.C. § 112, first paragraph.

**B. Enablement**

**1. *Claim 23***

Claim 23 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. While not acquiescing to the argument that a deposit is needed to satisfy any requirements under 35 U.S.C. § 112, Applicants respectfully submit that microorganism NCIMB 41011 was deposited under the terms of the Budapest Treaty with a international depositary authority in the United Kingdom, National Collections of Industrial, Food and marine Bacteria (NCIMB), before the filing of the application. Applicants submit with this amendment a copy of the deposit receipt (Exhibit A) for NCIMB 41011 together with a declaration under 37 C.F.R. § 1.132 (Exhibit B) as to accessibility of the deposited microorganisms. The declaration clearly confirms that a deposit of the subject microorganism, *i.e.*, NCIMB 41011, has been made under conditions which would make it then available to the public as of the issue date of the patent granted, by irrevocably removing all restrictions imposed by the depositor on the availability to the public of the deposited material.

**2. *Claims 1-2, 5, 7-22 and 26***

Claims 1-2, 5, 7-22 and 26 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

The specification contains guidance to allow one of skill in the art to practice the claimed invention without undue experimentation. Some of the relevant criteria for determining whether or not undue experimentation is required were summarized in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir 1988). It is improper to focus on a single factor, as a determination that undue experimentation is required must be based on the evidence as a whole. *See* MPEP § 2164.01. Even if complex experimentation is required, the experimentation is not necessarily undue. *Id.*

**(1) Claim Scope**

Generally, the claims are drawn to a promoter comprising a nucleotide sequence corresponding to that shown in SEQ ID No. 1 or a nucleotide sequence with at least 75% homology to SEQ ID No. 1. In addition, the claims are drawn to the promoter of claim 1 operably linked to SEQ ID Nos. 2 or 5 or a nucleotide sequence with at least 75% homology to SEQ ID Nos. 2 or 5. The claims are also drawn to methods and constructs relating to the claimed promoters.

**(2) Guidance/Examples**

As noted by the examiner, the specification discloses numerous specific examples of how to make and use the claimed subject matter. *See* Office action at 9. The examiner also alleges that “[t]he specification does not disclose how to make and use” the remaining promoters claimed. However, this statement is incorrect. The specification does in fact disclose ways of obtaining the claimed genus of species, including tests for function. *See*, e.g., page 24, ll. 22-26; page 25, l. 28 – page 26, l. 20; page 54, l. 29 – page 56, l. 9. The specification also extensively describes transformation and organisms to be transformed. *See*, e.g., page 39, l. 4 – 49, l. 10. These supplement the specific examples disclosed and the general knowledge of one of skill in the art.

**(3) State of the Art**

The examiner alleges that the state of the art is uncertain because promoter function cannot be predicted based on homology alone. However, the state of the art is such that homologs can be readily produced. In addition, methods exist, such as those described in the

specification (page 54, l. 29 – page 56, l. 9), to allow one of ordinary skill in the art to routinely screen sequences for activity. *See Ex parte Mark*, 12 USPQ.2d (BNA) 1904 (B.P.A.I. 1989) (holding that screening for biological activity is not undue experimentation).

**(4) Quantity of Experimentation**

As discussed in Section IV.B.2.(3) above, methods of obtaining promoters related to the specifically recited promoters are routine and largely automated. Similarly, the methods of screening homologous sequences for promoter activity are also routine and often at least partially automated. Even if complex experimentation is required, the experimentation is not necessarily undue. *See* MPEP § 2164.01.

**V. Claim Rejections – 35 U.S.C. § 112, second paragraph**

**A. Claim 5 & 23 - “obtainable from”**

Claims 5 and 23 stand rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for reciting “obtainable from.” While not acquiescing in the propriety of the rejection, Applicants amend claims 5 and 23 to recite “obtained” rather than “obtainable from” to expedite prosecution. Thus, Applicants respectfully request that this ground of rejection be reconsidered and withdrawn.

**B. Claims 9 & 14 – “the promoter of the present invention”**

Claims 9 and 14 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting “the promoter of the present invention,” because the examiner alleges the phrase lacks sufficient antecedent basis. While not acquiescing in the propriety of the rejection, Applicants amend the claims to remove the phrase “of the present invention.” Thus, Applicants respectfully request that this ground of rejection be reconsidered and withdrawn.

**C. Claim 15 – “but wherein”**

Claim 15 stands rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for reciting “but wherein.” While not acquiescing in the propriety of the rejection,

Applicants amend the claims to remove the word “but.” Thus, Applicants respectfully request that this ground of rejection be reconsidered and withdrawn.

**D. Claims 16-18 – “the invention according to claim 1”**

Claims 16-18 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting “the invention according to claim 1” because the examiner alleges the phrase lacks sufficient antecedent basis. While not acquiescing in the propriety of the rejection, Applicants amend the claims to replace the phrase “the invention according to claim 1” with “the promoter according to claim 1.” Thus, Applicants respectfully request that this ground of rejection be reconsidered and withdrawn.

**E. Claims 20 & 22 – method steps**

Claims 20 and 22 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for allegedly “omitting essential steps.” Office action at 14. Applicants respectfully disagree.

While not acquiescing to the rejection, Applicants have amended the claims to recite “causing the expression....” A skilled artisan would readily understand the variety of means by which expression can be caused and would be able to cause the expression. Similarly, in regard to claim 20, a skilled artisan understands a variety of methods to isolate an expressed polypeptide, such as the methods described in the specification. Accordingly, the claims are both clear and definite, because a skilled artisan would understand the metes and bounds of the claimed subject matter. Thus, Applicants respectfully request reconsideration and withdrawal of this ground of rejection against claims 20 and 22.

**F. Claim 26**

Claim 26 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. While not acquiescing in the propriety of the rejection, Applicants have cancelled claim 26. Thus, the rejection is moot.

**VI. Claim Rejections – 35 U.S.C. § 101**

Claims 1-14, 23, and 26 stand rejected under 35 U.S.C. § 101 because the invention is allegedly directed to non-statutory subject matter. While not acquiescing on the propriety of the rejection, Applicants have amended the claims to recite “isolated,” to expedite prosecution.

**VII. Claim Rejections – 35 U.S.C. § 102**

**A. Wing et al.**

Claims 1-2, 5, 7, 15-19, and 26 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by Wing *et al.*, “A BAC End Sequencing Framework to Sequence the Rice Genome,” Database EMGSS3 ‘Online! (1998) EMBL Heidelberg, Germany (Abstract) (“Wing”). Specifically, the Examiner alleges that Wing comprises nucleotides 29 to 58 of SEQ ID NO: 1. Furthermore, the Examiner presumes the sequence of Wing is a promoter because of sequence motifs characteristic of promoters. Applicants respectfully traverse this ground of rejection.

The sequence of Wing does not teach SEQ ID No. 1 or a sequence with at least 75% sequence homology to SEQ ID No. 1, as presently claimed. Thus, Wing does not teach or suggest the claimed invention. Applicants respectfully request reconsideration and withdrawal of this ground of rejection under 35 U.S.C. § 102.

**B. Invitrogen Catalogue 1997**

Claim 24 stands rejected under 35 U.S.C 102(b) as allegedly anticipated by the Invitrogen Catalogue 1997 (“Original TA Cloning Kits, pCR2.1 vector,” page 7). While not acquiescing in the propriety of the rejection, claim 24 has been cancelled. Thus, the rejection has been rendered moot.

**CONCLUSION**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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